




# UNITED STATES PATENT AND TRADEMARK OFFICE

  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

|                                                                                                      |             |                      |                               |                  |
|------------------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------------|------------------|
| APPLICATION NO.                                                                                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
| 10/528,460                                                                                           | 12/19/2005  | Stefan Golz          | Le A 36 282<br>(004974.01083) | 7581             |
| 22907 7590 02/08/2007<br>BANNER & WITCOFF<br>1001 G STREET N W<br>SUITE 1100<br>WASHINGTON, DC 20001 |             |                      | EXAMINER<br>SHEN, BIN         |                  |
|                                                                                                      |             |                      | ART UNIT                      | PAPER NUMBER     |
|                                                                                                      |             |                      | 1657                          |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE                                                               |             | MAIL DATE            | DELIVERY MODE                 |                  |
| 3 MONTHS                                                                                             |             | 02/08/2007           | PAPER                         |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/528,460

Applicant(s)

GOLZ ET AL.

Examiner

Bin Shen

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

In view of the amended claims 1, 5, and arguments presented of record, the rejection under 35 USC § 112, second paragraph is hereby withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuasa et al. (JBC 2000;275(40):31469-31479).

Yuasa et al. teach a method of screening for agents useful in the treatment of a disease comprising: contacting a test compound with a PDE11A polypeptide; detect binding of the compound to PDE11A polypeptide (page 31473, left column, 3<sup>rd</sup> full paragraph, page 31476, left column, 1<sup>st</sup> full paragraph and Table II), wherein His-tagged (detectable label) human PDE11A is expressed and cytosolic extract is prepared from COS-7 cells (in vitro cell-free system), incubated with [<sup>3</sup>H]cGMP or [<sup>3</sup>H]cAMP (detectable label), and then counted on a scintillation counter, (see page 31470, right column, 4<sup>th</sup> full paragraph, also page 31473, left column 3<sup>rd</sup> full paragraph, and Table II).

Therefore, the cited reference is deemed to anticipate the instant claims above.

Art Unit: 1657

Applicant's arguments filed 1/1/2007 have been fully considered but they are not persuasive.

Applicant argues that Yuasa does not disclose step iii) of claim 1, and that Yuasa teaches that the physiological role for PDE11A is unknown.

It is the examiner's position that Yuasa teaches each PDE plays a distinct physiological role in different tissues and cells and may be valuable pharmacological targets (for treating PDE related diseases-page 31469, right column, 2nd full paragraph), and that PDE inhibitor inhibit the proliferation and invasive potential of cancer cells (page 31478, right column, lines 1-4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuasa et al., in view of Lanfear et al. (US2002/0115176A1).

Yuasa teaches what is above.

Yuasa does not teach that the contacting step is in or at the surface of a cell, the polypeptide is attached to a solid support, the compound is attached to a solid support.

Art Unit: 1657

Lanfear teaches a method of identifying agents that affect the activity of PDE11 and/or the expression thereof comprising adding agent in a cell line that expresses PDE11 (see paragraph [0515]), test compound are synthesized on a solid substrate ([0526], lines 6-7), purified PDE11 can also be coated directly onto plates for screening ([0526], lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Yuasa by attach the polypeptide and compound to solid supports because Lanfear teaches the benefit of using solid support for high throughput screening of compounds having suitable binding affinity to the PDE11 ([0526], lines 1-5). One would have been motivated to make the modification because Yuasa et al. specifically described the method of screening for PDE11A inhibitors and Lanfear teach that attachment to solid support make it possible for high throughput screening, and would reasonably have expected success in view of Yuasa' teaching that analysis of selective inhibitors for PDEs will elucidate new physiological functions of cAMP/cGMP in prostate and testis (end of page 31478), and Lanfear's teaching that inhibitors of PDEs will lead to more effective therapy with fewer side effects [0008]. The adjustment of particular conventional working conditions (e.g., the step of contacting is in or at the surface of a cell) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to

Art Unit: 1657

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 1/1/2007 have been fully considered but they are not persuasive.

Applicant argues that Yuasa and Lanfear do not disclose step iii) of claim 1.

It is the examiner's position that Yuasa teaches each PDE plays a distinct physiological role in different tissues and cells and may be valuable pharmacological targets (for treating PDE related diseases-page 31469, right column, 2nd full paragraph), and that PDE inhibitor inhibit the proliferation and invasive potential of cancer cells (page 31478, right column, lines 1-4), and that Lanfear's teaching that inhibitors of PDEs will lead to more effective therapy with fewer side effects [0008].

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1657

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Conclusion**

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office..

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

Art Unit: 1657

problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

*Ralph Gitomer*

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200

B Shen

Art Unit 1657